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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,449	01/12/2004	Steve Dunfield	200208788-1	2134

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INTELLECTUAL PROPERTY ADMINISTRATION
FORT COLLINS, CO 80527-2400

EXAMINER

ROBINSON, JAMES MARSHALL

ART UNIT	PAPER NUMBER
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3772

NOTIFICATION DATE	DELIVERY MODE
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06/25/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/756,449	Applicant(s) DUNFIELD ET AL.	
	Examiner James M. Robinson	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-15,46-48 and 53-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-15,46-48 and 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to amendments/arguments filed 04/09/2009. Currently claims 1, 3-7, 9-15, 46-48, and 53-58 are pending in the instant application. It is noted that applicant amended claims 1, 14, 15 and 53-57. New claim 58 has been added.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/09 has been entered.

Response to Arguments

1. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1 the limitation -- wherein ejecting medicament droplets includes ejecting droplets that include a bioactive agent in each of a pair of doses requested by the subject, wherein the pair of doses has an elapsed time between the doses, and wherein a droplet size of the droplets including the bioactive agent ejected in a later dose of the pair of doses is selected by the ejection apparatus based on the elapsed time -- renders the claim indefinite. Specifically, the recitation "a pair of doses requested by the subject" is unclear. The first limitation, which controls the claimed method of dispensing one or more medicaments recites "providing a treatment plan having at least two rates of action for one or more medicaments". However, the amended claim now recites a pair of doses requested by the subject. Thus, as a result of the amendment, claim 1 is indefinite because it is unclear how this pair of doses requested appertains to the treatment plan. It is uncertain if this "pair of doses" is part of the treatment plan or separate or in conjunction with the treatment plan. Further complicating clarity of the claim is the recitation to "the pair of doses is selected by the ejection apparatus based on the elapsed time". So now it appears there are 3 competing dispensing regimes: 1. treatment plan, 2. subject request, 3. ejection apparatus selection based on elapsed time. Appropriate correction is requested in order to reconcile the apparent competing dispensing mechanisms. In order to further prosecution, as best as can be understood by examiner, the method of dispensing comprises a treatment plan having at least two rates of action including a pair of doses selected based on elapsed time.

With respect to claim 58, the recitations "ejecting relatively larger and relatively smaller droplets" and "above a threshold" render the claim indefinite. It is unclear what applicant is relating the size of the droplets to. It is unclear what the size of the medicament droplets are relative to. Are the droplets relative to themselves? Are these the droplets referred to as a pair of doses requested by the subject? Further, what is the threshold. It is impossible for one of ordinary skill in the art to define the metes and bounds of "a threshold" when no quantitative minima or maxima has been clearly defined. Appropriate correction is respectfully requested.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3-7, 9-15, 46-48, and 53- 54 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges (US 5894841) in view of Blakley et al (US 6830046).

Voges discloses a method of dispensing one or more medicaments (col. 12, lines 9-13), comprising: providing a treatment plan having at least two rates of action for one or more medicaments (col. 11 line 66- col. 12 line 2); selecting a different droplet size characteristic corresponding to each of the at least two rates of action; and ejecting medicament droplets having each different droplet size (col. 8, lines 45-51)

characteristic into a respiratory system of a subject (col. 5, lines 20-25) according to the treatment plan, thereby allowing the one or more medicaments to act at two or more rates; wherein selecting the different droplet size includes selecting a droplet size according to a predicted change in the droplet size produced during flight (col. 7 lines 4-15) of the medicament droplets after ejection;

Voges further discloses wherein ejecting medicament droplets includes ejecting medicament droplets having each different droplet size (col. 8, lines 45-51) characteristic from a distinct set of orifices (col. 4, lines 53-58) of the same medicament ejection apparatus; wherein selecting the different droplet size characteristic includes selecting a different medicament composition (col. 7, lines 15-29) for each rate of action, and wherein ejecting medicament droplets includes ejecting medicament droplets having each different medicament composition; wherein selecting the different medicament composition includes selecting the same bioactive agent (col. 7, lines 4-14) for each different medicament composition; wherein selecting the different droplet size includes selecting a size of medicament droplet according to a deposition site (col. 8, lines 22-27) for the size of medicament droplet in the respiratory system, the deposition site defining an absorption rate that corresponds to one of the at least two rates of action, wherein ejecting medicament droplets includes forming medicament droplets of each droplet size adjacent orifices (col. 8, lines 45-51) of a corresponding size; wherein ejecting medicament droplets includes ejecting medicament droplets of different sizes at nonoverlapping times (col. 7, lines 36-41); wherein ejecting medicament droplets includes ejecting medicament droplets of each different droplet size within the same

dose (col. 8, lines 45-51); selecting a composition for each different droplet size (col. 11 line 66- col. 12 line 2); wherein the composition is selected from compositions having different amounts of the same bioactive agent; (col. 7, lines 15-29); wherein ejecting medicament droplets includes ejecting the same medicament composition for each different droplet size characteristic (col. 11 line 66- col. 12 line 2);

Voges further discloses wherein providing the treatment plan includes providing a treatment plan to treat addiction to nicotine, and wherein at least one of the medicaments includes nicotine (col. 6, lines 17-19) or a nicotine analog; wherein ejecting medicament droplets includes ejecting medicament droplets targeted for deposition on respective upper and lower mucosal regions of the respiratory system; wherein ejecting medicament droplets includes ejecting medicament droplets of different droplet sizes targeted for deposition on an oral or nasal mucosal region and a pulmonary (col. 1, lines 61-66) mucosal region; wherein selecting the different droplet size includes selecting a medicament composition with the same drug for each different droplet size. wherein selecting the different droplet size includes selecting a medicament composition with the same drug for each different droplet size (col. 8, lines 45-51); wherein ejecting medicament droplets includes ejecting medicament droplets having a drug and a flavoring agent (col. 8, lines 39-44).

With respect to claim 1, Voges further discloses wherein ejecting medicament droplets includes ejecting droplets that include a bioactive agent in each of a pair of doses requested by the subject (col 5 ln 8-19), wherein the pair of doses has an

elapsed time between the doses. However, Voges fails to explicitly disclose wherein a droplet size of the droplets including the bioactive agent ejected in a later dose of the pair of doses is selected by the ejection apparatus based on the elapsed time.

However, Blakley et al. discloses a metered dose inhaler including an ejection mechanism and a processor configured to alter the dosage released by the inhaler during a dosage regimen in a case where it is desirable to gradually increase or gradually decrease the dosage during the course of treatment (col. 8 ln 43-63).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method steps of dispensing one or more medicaments disclosed by Voges with the parameters of the dosage regimen taught by Blakley in which a pair of doses are capable of being selected based on an elapsed time since it is essential that elapsed time between any and all doses is considered when electing a treatment plan in order to ensure that a toxic dose is not delivered as well as to enhance treatment plan efficacy. It is necessary, required, and prudent that a skilled practitioner consider all temporal factors when designing droplet and dosage size delivery in the context of a medicament treatment plan in order to enhance the therapeutic effects on a user.

6. Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges (US 5894841) in view of Blakley et al (US 6830046) and further in view of Childers et al. (US 6886557). The combination of Voges and Blakley substantially disclose the invention as claimed; see rejection to claim 1 above. However, Voges/Blakley are silent to ejecting placebo droplets without the drug and sized for

deposition on an oral mucosal region instead of ejecting medicament droplets having the drug.

Childers et al. discloses a method for delivering multiple inhalable materials in programmably varying amounts over time (col. 1, lines 50-51) including first and second microfluidic generators or emitters (col. 1, lines 51-55) which utilizes ejection of materials which are considered pharmacologically inactive; wherein placebos are administered instead of drug medicament droplets having a drug in order to provide user with a measure of satiation or satisfaction. (col. 5 line 64- col. 6 line 5).

It would have been obvious to modify the method of Voges/Blakley to include ejecting placebo droplets without the drug and sized for deposition on an oral mucosal region instead of ejecting medicament droplets having the drug as taught by Childers in order to utilize provide psychological satisfaction to a user while limiting the amount of drug delivered in order to wean a user off of cigarettes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Robinson whose telephone number is (571) 270-3867. The examiner can normally be reached on Mon-Fri 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James M. Robinson/

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772